**From:** Dipanjana Bhattacharya
**To:** Rafael Casanova
**Cc:** Garyg Miller
**Subject:** Re: Gulfco - Human Health Uncertainty Section and Summary
**Date:** 05/26/2011 02:35 PM
**Attachments:** Risk Assessment Section of Gulfco Proposed Plan.docx

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Rafael,

I am sending you the final draft so far. I edited your sections and included them in the summary of site risks.

Dipanjana

Risk Assessment Section of Gulfco Proposed Plan.docx

▼ Gulfco - Human Health Uncertainty Section and Summary

**Gulfco - Human Health Uncertainty Section and Summary**

**Rafael Casanova** to: Dipanjana Bhattacharya 05/26/2011 10:46 AM

Cc: Garyg Miller

Dipanjana, following is the uncertainty section of the Proposed Plan. I think it's too long. Please see how we can shorten it, but still provide the necessary information to the public.

Also, please take a look at the summary at the end. Thanks.

**Uncertainty Analysis for Human Health Risk Assessment**

The HHRA included an "**uncertainty** analysis." The objective of the analysis is to provide decision makers with a summary of those factors that significantly influence the risk results, evaluate their range of variability, and assess the contribution of these factors to the potential underestimation or overestimation of overall HHRA results. Virtually every step in the HHRA process requires numerous assumptions, all of which contribute to uncertainty in the risk evaluation. In the absence of empirical or site-specific data, assumptions are developed based on best estimates of data quality, exposure parameters, and dose-response relationships. To assist in the development of these estimates, the EPA provides guidelines

and standard default exposure factors to be used in HHRAs. The use of these standard factors is intended to promote consistency among risk assessments where assumptions must be made. However, their usefulness in accurately predicting risk depends on their applicability to the site-specific conditions. It is likely therefore, that the net effect of all the assumptions yields a conservative estimate of overall HHRA results; that is, total risk/hazards are more likely than not to be overestimated.

Sources of uncertainty include (1) data analysis, (2) exposure analysis, (3) toxicity assessment, and (4) risk characterization. These uncertainties result in either over- or under-estimation of actual risks, depending on the specific factor.

**Data Analysis Uncertainties**

Overall, the data were determined to be of high quality. Data were collected, analyzed, and validated in accordance with EPA-approved procedures. Very few of the data for any of the analytes were found to be unusable (*i.e.*, "R-flagged"). In instances where data were unusable, the analysis was conducted again, whenever possible, and the R-flagged data was not used. Some of the data are qualified (*i.e.*, "J-flagged") as estimated because the measured concentration is above the sample detection limit but below the sample quantitation limit and/or due to minor quality control deficiencies. According to the EPA's guidance, data that are qualified as estimated can be used for risk assessment purposes.

Compounds were eliminated from further quantitative evaluation in the HHRA if they were determined to be statistically no different than background concentrations. While this may result in an under-estimation of overall Site risks, this approach is appropriate for this Site given that there is no identifiable source of metals at the Site and, regardless, very few inorganic organic compounds were measured above $1/10^{th}$ of their respective screening criteria.

**Exposure Analysis Uncertainties**

The EPA's risk assessment guidance for exposure assessments generally requires standard hypothetical exposure scenarios rather than realistic site-specific evaluation of exposure, and this conservative default approach was used for the future industrial and construction worker scenarios. Under this approach, if a chemical is found to be present at a site, it is assumed that exposure to that chemical will occur regardless of whether that exposure is realistic or likely. Uncertainties associated with the exposure assessment included calculation of exposure point concentrations (EPCs) and selection of exposure parameters. For example, the intake equations are based on several $95^{th}$ percentile values. When multiplied together, these data compound the uncertainties in the exposure assessments and result in estimated intakes, and resultant cancer risks, that likely estimate exposure well over the $95^{th}$ percentile.

It is difficult to assess the likelihood of any of the hypothetical future scenarios occurring (*i.e.*, future construction worker or future industrial worker) nor is it possible to know the extent, if any, that trespassers and contact recreation receptors are exposed to potential chemicals of concern (PCOC) at the Site. It was assumed that the youth trespasser accesses the Site once a week for twelve years. It was assumed that the contact recreation scenario receptor visits the Site for 39 times per year for 25 years. The exposure assumptions used for all scenarios were conservatively chosen to purposefully over-estimate exposure. For the

current scenarios *(i.e.*, the youth trespasser and the contact recreation scenario) it appears that these represent a bounding estimate since exposure is likely to be much less.

The screening conducted to evaluate off-site impacts from particulate dust generation and VOC emissions and migration was very conservative because it did not assume any dispersion during transport. Despite that very conservative assumption, no adverse risks to off-site residents were likely.

Soil ingestion rates for adults and older youth are highly uncertain. Because the ingestion rate is a very sensitive parameter in the intake equation, uncertainty and variability in this assumption has a large impact on the dose estimate. This is especially relevant for the construction worker scenario when an enhanced ingestion rate was used. The uncertainty related to this value is high given the study design, small study population, and limited exposure length that are the basis for the soil ingestion rate.

Assumptions regarding bioavailability of metals in soil can significantly influence risk estimates. The EPA typically assumes that the bioavailability of compounds from soil is equal to that observed in the toxicity studies used to derive oral toxicity factors, but this is most often not the case. Rather, toxicity studies are often, if not always, conducted using a concentration of a compound in either food or water. Bioavailability was assumed to be 100%, although it is well known that metals and some organic compounds bound to soil are less than 100% bioavailable. This assumption leads to an over-estimation of risks, which can be significant.

In the fish tissue risk assessment, ingestion rates for finfish were used to represent fish and shellfish ingestion rates, and site-specific fish and crab concentrations were used to estimate exposure. It is unlikely that there is significant uncertainty presented in the fish/shellfish ingestion risk assessment based on the uptake and bioaccumulation differences between crab, a crustacean shellfish, and oysters and clams, molluscan shellfish, since exposure to molluscan shellfish, if harvesting these species were allowed, would be similar if not the same as for the fish and crab, a crustacean shellfish, ingestion pathway.

For surface water and ground water, maximum concentrations were selected as the EPC for purposes of evaluating human health risks. This is likely to be a conservative approach since there were other, lower concentrations, also measured for these media. It is unlikely that surface water concentrations would increase in the future since surface runoff does not appear to be significantly impacting surface water, and impacted ground water does not discharge to surface water.

**Toxicity Assessment Uncertainties**

The studies/basis for the toxicity information and the use of this information generate uncertainty. Toxicity assessments for many of the PCOCs in the BHHRA involve the extrapolation of results from studies on animals. The following are standard assumptions applied by the EPA when extrapolating the results of studies of carcinogenicity in animals to humans.

- Any constituent showing carcinogenic activity in any animal species will also be a human carcinogen.

There is no threshold dose for carcinogens.

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- The results of the most sensitive animal study are appropriate to apply to humans.
- Humans are more sensitive than the most sensitive animal species on a body weight basis.

Uncertainties are introduced in animal to human extrapolation and high to low dose extrapolation. Mathematical models are used by the EPA to estimate the possible responses due to exposure to chemicals at levels far below those tested in animals. These models contain several limitations, which should be considered when the results (*e.g.*, risk estimates) are evaluated. Primary among these limitations is the uncertainty in extrapolation of results obtained in animal research to humans and the shortcomings in extrapolating responses obtained from high-dose research studies to estimate responses at very low doses. For example, humans are typically exposed to environmental chemicals at levels that are less than a thousandth of the lowest dose tested in animals. Such doses may be easily degraded or eliminated by physiological internal mechanisms that are present in humans.

Additionally, approaches typically used for designating reference doses (RfDs) are highly conservative. For example, the EPA applies a factor of 10 to a No-Observable-Adverse-Effect-Level (NOAEL) for a compound in an animal study for animal-to-human extrapolation. An additional factor of 10 is applied for inter-individual variation in the human population, and additional factors of 10 may be applied to account for limitations in data quality or incomplete studies. Frequently, RfDs are derived from animal studies that have little quantitative bearing on potential adverse effects in humans. Some of this uncertainty may be reduced if the absorption, distribution, metabolic fate, and excretion parameters of a compound are known.

Potential long-term, or chronic, exposures are typically evaluated in risk assessments for Superfund sites, and chronic RfDs and reference concentrations (RfCs) are the appropriate toxicity criteria to apply to chronic exposure scenarios. Chronic exposure is defined by the EPA as greater than or equal to seven years. The BHHRA includes a construction worker scenario, which was assumed to be of a shorter duration than seven years and is, therefore, considered a subchronic exposure scenario. In some cases, the EPA provides recommended subchronic RfDs which are typically 10 times higher than chronic values. Only chronic toxicity values were used in the risk assessment, which imparts conservatism in the construction worker scenario.

**Risk Characterization Uncertainties**

The only instance where uncertainty may have been introduced into the risk assessment that is not considered conservative was when toxicity values or screening criteria were not available. This was only an issue when evaluating impacts to off-site receptors since there are not inhalation toxicity values for many of the compounds (or TCEQ PCLs) and, as such, a comparison could not be made. It is believed that this is insignificant since: 1) there are few VOCs present in soil at the South Area, 2) the VOCs that are present were measured in low concentrations, and 3) surficial soil testing for lead on Lots 19 and 20 did not suggest that off-site migration via fugitive dust generation was a significant concern.

It was estimated that risks associated with VOC emissions from shallow Zone A groundwater to future inhabitants of buildings were above the EPA's target risk goals. It should be noted that this is a highly uncertain pathway with the use of many default assumptions to calculate risks since currently the pathway is incomplete (*i.e.*, there is no building or no worker at the Site 250 days per year for exposure to occur). Likewise, conservative assumptions were made about the slab and slab integrity and contaminant transport in the vapor intrusion model that would greatly affect the resulting risk estimates. Therefore, it is advisable to consider the results of this analysis in light of the substantial amount of uncertainty in the underlying assumptions of this pathway.

**Impact of Uncertainties**

Efforts were made in the BHHRA to purposefully err on the side of conservatism in the absence of site-specific information. It is believed that the overall impact of the uncertainty and conservative nature of the evaluation results in an overly protective assessment. Therefore, for scenarios with risks and HIs within or below the Superfund risk range goal and target HI, it can be said with confidence that these environmental media and areas do not present an unacceptable risk.

**Conclusions of the Human Health Risk Assessment**

The primary objective of this BHHRA was to evaluate the possible risks associated with PCOCs in environmental media on human receptors at the Site. Five different exposure scenarios were quantitatively evaluated for the thirteen different potentially contaminated media identified at the Site. Exposure scenarios were developed to describe current and potential future land use by various human receptors and included a future industrial worker, future construction worker, current youth trespasser, current contact recreation receptor, and current off-site residential receptor. Exposure and risks were calculated for both central tendency and reasonable maximum exposure (RME) scenarios.

Based on the risk estimates and hazard indices, there were not unacceptable cancer risk or noncancer hazard indices for any of the current or future exposure scenarios except for future exposure to an indoor industrial worker if a building is constructed over impacted ground water in the North Area. Potential cancer risks in the North Area using maximum shallow Zone A ground water concentrations and the vapor intrusion model were predicted to be greater than $1.0 \times 10^{-4}$ while the HIs were estimated to be greater than 1.0. It should be noted that this scenario was evaluated despite the current restrictive covenant on Lots 55, 56, and 57 that require future building design to preclude vapor intrusion, which would effectively make this pathway incomplete. Estimated risks from Zone A ground water at the South Area were below the EPA's goals and, therefore, adverse risks associated with the vapor intrusion pathway are unlikely in this area.

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Assigned Sites for Investigation and Remediation:
(http://www.epa.gov/earth1r6/6sf/6sf-tx.htm):
Brine Service Company Superfund Site (Corpus Christi, Texas)
Falcon Refinery Superfund Site (Ingleside, Texas)
Many Diversified Interests, Inc. Superfund Site (Houston, Texas)
Palmer Barge Line Superfund Site (Port Arthur, Texas)
State Marine of Port Arthur Superfund Site (Port Arthur, Texas)